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Attorneys for Defendants
C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability
Litigation

No. 2:15-MD-02641-DGC

**DEFENDANTS' MOTION AND
INCORPORATED MEMORANDUM
TO SEAL DOCUMENTS LODGED
UNDER SEAL BY PLAINTIFFS IN
OPPOSITION TO DEFENDANTS'
MOTION FOR SUMMARY
JUDGMENT REGARDING
PREEMPTION**

(Assigned to the Honorable David G.
Campbell)

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively
“Bard” or “Defendants”) hereby submit this Motion to Seal and Memorandum relating to
documents lodged under seal by Plaintiffs in Opposition to Defendants’ Motion for

Summary Judgment Regarding Preemption. Plaintiffs lodged documents under seal both in relation to Plaintiffs Separate Statement of Facts in Support of Their Opposition to Defendants' Motion for Summary Judgment Regarding Preemption (Dkt. 7370, 7371, 7372 and 7373) Plaintiffs' Controverting Statement of Facts in Opposition to Bard's Motion for Summary Judgment Regarding Preemption (Dkt. 7474, 7375 and 7376) and Plaintiffs Errata. (Dkt. 7666).

Bard has reviewed the documents lodged under seal in the three filings. Attached as Exhibit 1 is the Declaration of Robert Carr. Exhibit A to his Declaration, are lists of the documents at issue using the Exhibits to Plaintiffs' Notices of Lodging (Dkt. 7371 and 7375). The documents Bard is not seeking to seal have "WITHDRAWN" next them. Additionally, Bard has redacted most of the remaining documents so that only the trade secrets and confidential information as described in the Carr Declaration. They are marked "SUBMITTED REDACTED" and Bard has filed the proposed redacted versions. (Dkt 7845). Finally Bard seeks to have five documents remained sealed in their entirety. They are highlighted on Exhibit A to the Carr Declaration.

1. Documents Bard submitted redacted (Dkt. 7845)

Exhibit 1-B and 1-C are expert reports for Plaintiffs' retained regulatory expert Dr. David Kessler. He quotes from hundreds of Bard documents regarding design and testing of Bard's seven generations of filters, and documents created by Bard during the regulatory clearance applications for each of them. Bard has redacted information that reveals the information identified in Paragraph 3 of the Carr Declaration.

Exhibit 2-A is the report of Bard's regulatory expert, Dr. Christine Brauer. Bard redacted her references to Bard's internal testing and analysis of its filters.

Exhibit 2-E and 2-F in Dkt 7845 are filed redacted are test protocol reports for testing and analysis performed by Bard on IVC filters. Bard redacted those consistent with FOIA redactions. These were filed with Plaintiffs' Errata (Dkt. 7666) and are referred to as Exhibit E and F thereto. They are not referenced on Exhibit A to the Carr Declaration.

1 Exhibit 2-F is two reports of studies performed by Bard during the development
2 and analysis of its IVC filter. Bard redacted those studies consistent with FOIA redactions
3 to protect internal testing and analysis. .

4 Exhibits 2-H, 2-J and 2-M are all internal Bard documents that were not provided
5 to the FDA. Bard redacted those documents to protect internal testing and analysis,
6 marketing and regulatory analysis and decisions.

7 **2. Documents Bard is seeking to seal entirely**

8 Exhibit 2 on Page 1 of Exhibit 1 is an internal Bard sales communication used or
9 educate the sales force. It was not publically available and contains Bard's sales and
10 marketing strategy.

11 Exhibits 2-N, 2-O, 2-P and 2-V on Page 2 of Exhibit 1 are internal testing and
12 analysis of Bard filters created during the development of the filters.

13 The redactions and the documents Bard seeks to seal are limited to Bard's trade
14 secrets and confidential commercial information and are consistent with the exemptions to
15 the Freedom of Information Act. (Carr Decl 3.) The redacted and sealed information
16 contained in the documents required years for Bard to develop and is Bard's critical
17 business information which is not made public by Bard; would be of economic value to
18 Bard's competitors. Moreover, such value would extend not only to manufacturers of
19 other IVC filters. Bard invests very substantial sums of money in medical device research,
20 testing (including clinical testing), development, design, analysis, regulatory compliance,
21 product evaluation, and marketing. If the information Bard has developed over the years
22 pertaining to the Bard IVC Filters was obtained by its competitors, it would give an unfair
23 economic advantage to those competitors. (*See*, Carr Decl.)

24 Protecting such information from public disclosure and from Bard's competitors
25 will prevent Bard from sustaining serious economic and competitive harm, thereby
26 representing a compelling reason to protect the documents' confidentiality. Further, while
27 protecting Bard's confidential information, the redactions and documents under seal do
28 not impair the public's ability to understand the ruling by the Court on Bard's Motion for

Summary Judgment regarding Preemption. Accordingly, the Court should grant Bard's Motion to Seal.

ARGUMENT AND CITATION OF AUTHORITY

A. The Court should seal the redactions and the documents because the information is not necessary to understand any order on Bard's Motion for Summary Judgment.

In their response to Bard's Motion for Summary Judgment, their Statement of Facts in Support of Their Opposition to Bard's Motion and their Controverting Statement of Facts in Opposition to Bard's Motion, Plaintiffs refer to the documents at issue in this motion, but not to support their arguments or opposition. In fact in many instances, they simply cite to the fact that the document was created or exists. As such, the documents are not part of the analysis as to whether there is an issue of material fact, and are likewise not necessary for the Court to rule or for the public to be able to understand the ruling on Bard's Motion.¹ As redacted, the documents meet the test of the balance necessary between the right of public access and the right to protect materials that "have traditionally been kept secret for important policy reasons." as recognized in *Kamakana v. City & Cnty. of Honolulu*, 447 F.3d 1172 (9th Cir. 2006).

B. Compelling Reasons Exist to Seal the Redacted Information and the Sealed Documents

Although the Ninth Circuit recognizes that the public has a "general right to inspect and copy public records and documents, including judicial records and documents," *see, Kamakana*, 447 F.3d at 1179 (quoting *Nixon v. Warner Commc'ns, Inc.*, 435 U.S. 589, 597 & n. 7 (1978)), it also recognizes that the right of public access is not absolute and is overcome for materials that "have traditionally been kept secret for important policy reasons." *Id.* (quotation omitted).

¹ Bard objects to Plaintiffs simply citing to documents and filing them to put them in the public record without relying on them to support any factual allegation or claim, but nonetheless has redacted them and addresses them in this Motion.

Such compelling reasons for sealing documents exist, for example, regarding proprietary, trade secret, and technical information, and FDA submissions—the same type of information that Bard requests that the Court seal here. For example, in *In re Incretin-Based Therapies Products Liability Litigation*, No. 13MD2453 AJB (MDD), 2015 WL 11658712 (S.D. Cal. Nov. 18, 2015), the Court considered motions to seal related to cross-motions for summary judgment on the affirmative defense of preemption. The court found that compelling reasons existed to grant the motions to seal because the information was “confidential and proprietary information specific to each drug at issue and the development, testing, and regulation of each drug.” *Id.* at *3. The court found that such information “is readily subject to improper use resulting in significant competitive harm if disclosed publicly and available to competitors.” *Id.* Moreover, because the court’s analysis in resolving the underlying motions focused on FDA action, as opposed to an “evaluation or analysis of the specific data considered by the FDA,” disclosing the information publicly “would shed no light on the judicial process and bears the risk of causing confusion to the public through the limited disclosure of traditionally confidential data and regulatory submissions.” *Id.*

Similarly, in *Spectrum Pharmaceuticals, Inc. v. Sandoz Inc.*, No. 2:12-CV-00111-GMN, 2014 WL 4202540, at *2 (D. Nev. Aug. 21, 2014), the court considered documents submitted in support of Sandoz’s motion for summary judgment. The documents related to an Abbreviated New Drug Application to the FDA, technical information about the product, and specific efforts to obtain FDA approval of the Application, including actual and planned confidential communications with the FDA. *Id.* The court found that information of this nature could injure the parties’ business, thereby constituting a compelling reason to grant the motion to seal. *Id.*

C. The Redacted Information and Sealed Documents Contain Bard’s Trade Secrets and Other Confidential Information

The redacted information and documents that Bard seeks to seal are the same type of information that the *In re Incretin-Based Therapies* and *Spectrum Pharmaceuticals*

1 courts sealed at the dispositive motions stage. The redacted information and documents
 2 reflect confidential and proprietary information concerning the design, development,
 3 testing (including clinical testing), manufacture, and regulatory compliance activities
 4 concerning Bard IVC Filters; that detail Bard's product development activities,
 5 proprietary testing, and implementation of various proprietary processes and procedures.
 6 (Carr Decl. 3, 10). This redacted information and the documents took years for Bard to
 7 develop and reflect Bard's critical and confidential business information. (Carr Decl. 11,
 8 12 & 13). Moreover, the information would be of economic value to Bard's competitors,
 9 not just for IVC filters, but also to manufacturers of other medical devices, as the
 10 information contained in the documents is not limited to IVC filters. *Id.* Bard invests
 11 substantial amounts of money in medical device research, testing, clinical trials,
 12 development, design, analysis, regulatory compliance, evaluation, and marketing. *Id.*
 13 Thus, if Bard's competitors obtained these documents, they would have an unfair
 14 economic advantage over Bard. *Id.*

15 Further, the categories of redacted information and the sealed documents at issue
 16 have long been recognized as containing information that requires sealing. *See e.g.,*
 17 *Spectrum Pharm., Inc. v. Sandoz Inc.*, No. 2:12-CV-00111-GMN, 2014 WL 4202540, at
 18 *2 (D. Nev. Aug. 21, 2014) (sealing among other "proprietary business plans" and
 19 "business practices," "actual and planned confidential communications with the FDA");
 20 *Clark v. Metro. Life Ins. Co.*, 2010 WL 1006823 (D. Nev. Mar. 16, 2010) (sealing
 21 "confidential internal business deliberations, organization, and capabilities"); *See also,*
 22 *Bracco Diagnostics, Inc. v. Amersham Health Inc.*, CIVA 3-6025FLW, 2007 WL
 23 2085350 (D.N.J. July 18, 2007) ("regulatory correspondence" with the FDA, "cost and
 24 profit information," "unpublished clinical studies," and "internal analyses on products
 25 which are not intended for publication or dissemination"). *See also, Medicis Pharm.*
 26 *Corp. v. Acella Pharm., LLC*, CV 10-1780-PHX-JAT, 2012 WL 2260928 at *2 (D. Ariz.
 27 June 15, 2012) (sealing exhibits related to "Medicis' marketing strategy, Acella's product
 28 formulation,...various e-mails and deposition transcripts, viscosity test data, sales and

1 marketing information, and various other documents” because “[m]uch of this information
2 has been previously sealed by the Court, has been designated as confidential by the parties
3 pursuant to the protective order in this case, or could otherwise potentially harm the
4 parties if released publicly because of its confidential and sensitive nature.”).

5 For each category of information listed above, Bard has continually and
6 successfully made efforts to protect the information from its competitors, in part because
7 it could be used by competitors against Bard. (See Carr Declaration Dkt. 7355 - # at
8 13 & 14). Additionally, Bard maintains the confidentiality of the documents and has
9 always sought a Protective Order or Confidentiality Agreement during the course of civil
10 lawsuits in order to protect their confidential, proprietary and trade secret information. (Id
11 at 7). Therefore, Bard has taken reasonable efforts to maintain confidentiality of these
12 documents and they should remain confidential.

13 Finally, Bard invests substantial sums of money in medical device research, testing,
14 development, design, analysis, regulatory compliance, and evaluation of its products and
15 does not make such information public. Thus, there is no doubt that the proprietary
16 information which Bard seeks to protect constitutes an overriding interest warranting
17 protection.

18 **D. The Resulting Prejudice From Public Disclosure Requires This Court’s**
19 **Protection**

20 As stated above, the proprietary redacted and sealed information contains highly
21 confidential and sensitive information about Bard’s design, product development, and
22 testing about the Bard Filters, and allowing unrestricted access to this information would
23 cause real and tangible harm to Bard, especially because they are not offered by Plaintiffs
24 to address any material fact. *See e.g., In re Eli Lilly & Co., Prozac Products Liability*
25 *Litigation*, 142 F.R.D. 454, 460 (S.D. Ind. 1992) (holding pharmaceutical company would
26 suffer harm if the manufacturing process it has expended time and money on developing
27 became known to competitors); *Culinary Foods, Inc. v. Raychem Corp.*, 151 F.R.D. 297,
28 305 *order clarified*, 153 F.R.D. 614 (N.D. Ill. 1993) (“[D]isclosing Raychem’s product

1 design modification and changes would decrease Raychem's incentive to invest in safety
2 devices. Raychem's competitors would get free access to information which Raychem has
3 spent a great deal of time and money producing and protecting").

4 Bard invests considerable sums of money in medical device research, testing,
5 development, design, analysis, regulatory compliance and evaluation. (Carr Decl. 14).
6 There is no valid reason for Bard's competitors to obtain the results of Bard's product and
7 marketing development without having to incur similar expenditures in time and money,
8 since it would give them an unfair economic advantage. It is well documented that the
9 current market for pharmaceuticals and medical devices is highly competitive. *See, e.g., In*
10 *re Gabapentin Patent Litigation*, 312 F. Supp. 2d 653, 659 (D.N.J. 2004) (noting the
11 pharmaceutical industry is highly competitive and granted protective order). An
12 inadvertent disclosure, through open court records, of Bard's information to any of its
13 competitors would certainly injure Bard's interest. This heightened level of
14 competitiveness in the medical device market warrants protecting Bard's efforts in
15 developing such precise and valuable medical devices, such as the Bard Filters at issue
16 here. *See, e.g., In re Gabapentin Patent Litigation*, 312 F. Supp. 2d 653 (holding that
17 evidence supported finding that good cause existed for continued secrecy of materials).

18 To the contrary, because Bard has now redacted the documents, the public will not
19 be impaired in its ability to understand the ruling by the Court on Bard's Motion for
20 Summary Judgment Regarding Preemption.

21 CONCLUSION

22 Therefore, compelling reasons exist for protection of Bard's documents, and the
23 Court should grant Bard's Motion to Seal for the documents filed redacted in Dkt. 7845
24 and the redactions to Plaintiffs Separate Statement of Facts in Dkt. 7848. Bard also
25 respectfully requests that the Court enter an Order sealing the five documents Bard seeks
26 to seal in its entirety.

1 This 28th day of September, 2017.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on September 28, 2017, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

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